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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of

Applicant	:	Allan Lepine
Serial No.	:	09/163,778
Filed	:	September 30, 1998
Title	:	CANINE MILK SUBSTITUTE
Docket No.	:	IAM 0498 PA
Examiner	:	P. Dubois
Art Unit	:	1761

CERTIFICATE OF MAILING
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on October 30, 2000.

Susan M. Luna
Agent Susan M. Luna Reg. No. 38,769

Assistant Commissioner for Patents
Washington, D.C. 20231

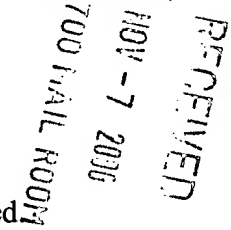
Sir:

BRIEF ON APPEAL

This is an appeal from the Office Action mailed June 6, 2000, finally rejecting claims 1 and 3-14 in the application. A Notice of Appeal was timely filed on August 29, 2000, with the accompanying fee. Our check in the amount of $310.00 accompanies this Brief in accordance with 37 CFR §1.17(c).

Real Party in Interest

The real party in interest in this application is The Iams Company, by assignment from the named inventor recorded in the files of the U.S. Patent and Trademark Office at Reel 9595, Frame 0600.



Related Appeals and Interferences

There are no related cases in which an appeal or interference has been filed.

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Status of the Claims

Claims 1 and 3-14 are pending in this application. Claim 2 was previously cancelled in the amendment filed September 28, 1999. Accordingly, claims 1 and 3-14 are before this Board for consideration on appeal. A copy of the appealed claims are found in Appendix A attached to this brief.

Status of Amendments

All of the amendments previously filed in this application have been entered. No amendments were filed subsequent to the final rejection.

Summary of the Invention

The present invention is directed to a canine milk substitute, or milk replacer, which has been formulated to contain amounts of protein, fat and carbohydrates which closely match the concentrations of those components in actual bitch milk. The composition comprises, on a dry matter basis, from about 35 to 45% by weight protein, from about 25 to 35% by weight fat, and from about 10 to 25% by weight carbohydrates. The protein source comprises casein and whey in a weight ratio of about 70:30. The composition also preferably contains about 27 to 37% by weight fatty acids and about 15 to 25% by weight essential amino acids (on a dry matter basis).

The canine milk substitute of the present invention, when fed to puppies in a quantity and frequency appropriate for their nutritional needs, has been found to provide greater daily weight gain and improved growth performance in those puppies as compared to commercially available milk replacers (see Example 3).

The canine milk substitute of the present invention was formulated based on a study of bitch milk which was undertaken to determine the concentrations of true protein, total fat, total carbohydrates, the casein to whey ratio, the amino acid profile, and the fatty acid profile (see the specification at pages 4-6). As a result, the canine milk substitute of the present invention duplicates canine milk more closely than currently available milk replacers (see Example 1).

For example, the composition of the present invention is higher in protein (about 38%) and lower in fat content (about 28%) than currently available milk replacers (about 29 to 34% protein and 33 to 42% fat).

Issues

The issues presented for review on appeal are:

1) Whether the Examiner erred in rejecting claims 1, 3-5 and 9 under 35 U.S.C. §103(a) as being unpatentable over Oftedal (Lactation in the Dog: Milk Composition and Intake by Puppies, p. 807) in view of Kakade, U.S. Patent No. 4,614,653.

2) Whether the Examiner erred in rejecting claims 6 and 14 under 35 U.S.C. §103(a) as being unpatentable over Oftedal in view of Kakade, U.S. Patent No. 4,614,653 and further in view of Gil et al., U.S. Patent No. 5,709,088.

3) Whether the Examiner erred in rejecting claims 7 and 11 under 35 U.S.C. §103(a) as being unpatentable over Oftedal in view of Kakade, U.S. Patent No. 4,614,653 and further in view of Gil, U.S. Patent No. 5,709,088 and Traitler et al., U.S. Patent No. 4,938,984.

4) Whether the Examiner erred in rejecting claims 8 and 12 under 35 U.S.C. §103(a) as being unpatentable over Oftedal in view of Kakade, U.S. Patent No. 4,614,653 and further in view of Kinumaki et al., U.S. Patent No. 4,294,856.

5) Whether the Examiner erred in rejecting claims 10 and 13 under 35 U.S.C. §103(a) as being unpatentable over Oftedal in view of Kakade and further in view of Fujimori, U.S. Patent No. 5,294,458.

Grouping of Claims

The Examiner has made five grounds of rejection, rejecting claims 1, 3-5 and 9 under 35 U.S.C. 103(a) as being unpatentable over Oftedal (Lactation in the Dog: Milk Composition and Intake by Puppies, pg. 807) in view of Kakade (U.S. Patent No. 4,614,653); claims 6 and 14 under 35 U.S.C. 103(a) as being unpatentable over Oftedal and Kakade and further in view of Gil

et al. (U.S. Patent No. 5,709,088); claims 7 and 11 under 35 U.S.C. 103(a) as being unpatentable over Oftedal, Kakade, and Gil and further in view of Traitler et al. (U.S. Patent No. 4,938,984); claims 8 and 12 under 35 U.S.C. 103(a) as being upatentable over Oftedal and Kakade and further in view of Kinumaki et al. (U.S. Patent No. 4,294,856); and claims 10 and 13 under 35 U.S.C. 103(a) as being unpatentable over Oftedal and Kakade and further in view of Fujimori (U.S. Patent No. 5,294,458).

The application contains three independent claims, namely, claims 1, 13 and 14. Applicant submits that the claims will not stand or fall together. The claims will be argued as grouped above, with the patentability of independent claims 1, 13 and 14 as well as dependent claims 3-12 being separately argued.

The References

Oftedal, "Lactation in the Dog: Milk Composition and Intake by Puppies", J. Nutr. Oftedal is directed to a study measuring the composition and intake of milk by mother-reared puppies. The results at page 805 indicate that the dog milk was found to contain about 41.4% fat and about 33.4% protein.

Kakade, U.S. Patent No. 4,614,653. Kakade teaches a milk replacer for monogastric animals which can be readily diluted to a solids content which approximates cow's milk. The milk replacer includes 10-45% sugars, 10-16% protein, and 1-25% fat (on a liquid basis).

Gil et al, U.S. Patent No. 5,709,088. Gil et al. teach a formula for infants and adults containing fat mixtures which include arachidonic acid and docosahexaneoic acid.

Traitler et al., U.S. Patent No. 4,938,984. Traitler et al. teach a nutritional composition which may be used in a variety of food supplements including infants' milk or animal feeds which includes omega 3, omega 6 and trans fatty acids.

Kinumaki et al., U.S. Patent No. 4,294,856. Kinumaki et al. teach a milk replacer for infant animals such as pigs and calves which contains amino acids.

Fujimori, U.S. Patent No. 5,294,458. Fujimori teaches a pet food for dogs and cats which may contain fructooligosaccharide.

Summary of Argument

The Examiner has failed to establish a prima facie case, by evidence or reasoning, that claims 1 and 3-14 would have been obvious with respect to the proposed combination of references. The Examiner has ignored the fact that none of the references are directed to compositions which are intended to duplicate bitch milk, nor do they teach or suggest a composition which includes the claimed protein levels or the claimed ratio of casein/whey. Further, the Examiner has provided no motivation or reasoning for one skilled in the art to modify the references to meet the claimed composition.

ARGUMENT

I. The Examiner's burden of establishing a prima facie case of obviousness has not been met.

It is well established that the burden of establishing a prima facie case of obviousness resides with the Examiner. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Piasecki, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984). This burden can be satisified only by showing some objective teaching in the prior art, or that knowledge generally available to one of ordinary skill in the art, would lead that individual to the claimed invention. Both the teaching and a reasonable expectation of success must be found in the prior art, not in applicants' disclosure. In re Vaeck, 20 USPQ2d 1438 (Fed.Cir. 1991).

Where the teachings of references are proposed to be combined, it is encumbent upon the Examiner to explain why the combination of reference teachings is proper. The suggestion to

modify the reference teachings must come from the references themselves, not from applicants' disclosure. See In re Laskowski, 871 F.2d 115, 117, 10 USPQ2d 1397, 1398-99 (Fed. Cir. 1989); In re Fine, supra 837 F.2d at 1075 ("[T]eachings of references can be combined, only if there is some suggestion or incentive to do so. Here, the prior art contains none."); Uniroyal v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051, 5 USPQ2d 1434 (Fed. Cir.), cert. denied, 109 S. Ct. 75 (1988) ("When prior art references require selective combination...to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself. Something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination.") Applicants submit that the proposed combination of references here is not based on any objective teaching or suggestion in the references themselves, but rather is based on prohibited hindsight using the claimed invention as a blueprint. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 227 USPQ 543 (Fed. Cir. 1985).

Where no expressed teaching or suggestion is apparent from the references, the Examiner must establish, with evidence or reasoning, why one skilled in the art would have been led by the relevant teachings of the applied references to make the proposed combination. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984); ACS Hospital System, Inc. v. Montefiore Hospital, 732 F.2d 1572, 221 USPQ 929 (Fed. Cir. 1984). Simply because the reference teaching can be modified does not make it obvious to do so.

Applicants submit that upon close examination, the Examiner did not meet his burden of establishing a prima facie case of obviousness as to any of the claims on appeal.

II. Neither Kakade nor Oftedal provide the necessary motivation to provide a milk replacer for canines having the claimed protein level and the claimed ratio of casein and whey.

With regard to claims 1, 3-5 and 9, the Examiner has maintained that Oftedal teaches the fat, protein and carbohydrate levels of an animal milk, and that Kakade provides motivation to "optimize the ratio of the protein mix" because of his teaching of whey and casein proteins in a milk replacer.

Applicant first wishes to point out that neither Oftedal nor Kakade are directed to milk replacers for puppies which teach the protein level recited in claim 1, i.e., 35 to 45% protein. Oftedal does not teach or suggest a milk replacer, but rather discloses the results of studies of the composition of natural dog milk fed to mother-reared puppies. Thus, the primary reference relied upon by the Examiner to show the obviousness of the claimed invention is not a milk replacer! There is no teaching or suggestion in Oftedal of producing a milk replacer based on the results of the studies. While the Examiner suggests that it would have been obvious to simulate the milk taught by Oftedal, even if one skilled in the art were motivated to formulate a milk replacer based on Oftedal's studies (and the Examiner has failed to provide factual evidence of such motivation), the composition would have a fat level of around 41%, which is much higher than the claimed amounts of 25 to 35% (claim 1) or 28% (claim 4), and a protein level of around 33%, which is less than the claimed protein levels of 35 to 45% (claim 1) or 38% (claim 3). While the Examiner previously argued that two of the additional published data shown in Oftedal show higher protein levels (see Table 4, Ssubotin and Deniges), such data is based on studies conducted on only 12 samples and 2 samples, respectively, which studies were conducted in 1866 and 1935, respectively. As can be clearly seen, the majority of recent data including that of Oftedal reflect measured protein levels in natural milk which are lower than the claimed levels.

Kakade teaches a milk replacer for monogastric animals which may contain about 13.3% to 32% protein on a dry matter basis, which is also lower than the claimed protein levels. Kakade also teaches the inclusion of about 10 to 35% lactose, which is outside applicant's claimed range of 4 to 8% (claim 9). While the Examiner has taken the position that it would

have been obvious to "optimize" the amounts of these components, there is simply no motivation to do so as Kakade is not concerned with providing optimal nutrition in a milk replacer ***specifically formulated*** for puppies but rather is directed to a ***general*** milk replacer for monogastric animals. While the Examiner pointed out in the final rejection that canines are monogastric animals, there is no specific teaching in Kakade of feeding the milk substitute to canines. In fact, it appears that the monogastric animals referred to in Kakade are most likely farm animals. See col. 1, lines 18-19.

With regard to the claimed ratio of casein and whey in the composition, the Examiner has acknowledged that Oftedal is silent as to the specific type of proteins in a dog milk composition, but maintains that it would have been obvious to "optimize the ratio of the protein mix", referring to Kakade's teaching of the addition of casein and whey to a milk product. However, Kakade does not teach or suggest using the claimed ratio of casein and whey (70:30). In fact, the amounts taught in Kakade appear to be in direct contrast to the claimed ratio. See col. 2, lines 36-37 and col. 4, lines 25-28, which teach that the majority of proteins (about 60%) comprise whey protein and the remaining proteins are casein or other digestible proteins.

There is no teaching in Kakade which would motivate one skilled in the art to provide the claimed ratio of casein and whey for the purpose of providing a milk replacer for puppies. Nor is there any recognition in either Kakade or Oftedal that the claimed ratio of casein and whey is closest to the ratio provided by actual bitch milk (see the bitch milk composition set forth at page 5). Nor is there any recognition in the prior art that the claimed amounts and ratios provide improvements in daily weight gain and growth for puppies fed the milk replacer composition.

Claim 1 and claims 3-5 and 9, which depend therefrom, are clearly patentable over the combination of Oftedal and Kakade.

III. One skilled in the art would not look to a human infant formula to produce a milk replacer for puppies.

The Examiner has maintained the rejection of claims 6 and 14 as being unpatentable over Oftedal and Kakade further in view of Gil et al. While the Examiner has conceded that neither Oftedal nor Kakade teach a source of fat which includes arachidonic acid or docosahexaneoic acid, he has taken the position that it would have been obvious to do so in view of Gil et al., who teaches a human infant formula which includes from about 0.09 to 0.40% arachidonic acid and from about 0.36 to 0.51% docosahexaneoic acid. Again, there is no motivation to modify Kakade as Gil is directed to a nutritional formula for human infants or adults, not for puppies. Even if one were to include the fat sources taught by Gil et al. in Kakade's formulation, the present invention would not result as none of the references teach the claimed levels of protein or the claimed ratio of casein and whey for use in a canine milk substitute as recited in claim 1, from which claim 6 depends. Accordingly, claim 14 is also believed to be patentable for the reasons discussed above.

With regard to the rejection of claims 7 and 11 in view of Kakade, Oftedal, Gil and Traitler et al., the Examiner has taken the position that it would have been obvious to include omega 3, omega 6 and trans fatty acids to a milk substitute for dogs in view of Traitler et al., who teach a dietetic food supplement for humans such as infants' milk. Again, there is no motivation to provide such fatty acids in a milk replacer for **dogs**. Even if one were to do so, the claimed composition would not result as none of the references teach the claimed protein level and casein and whey ratio recited in claim 1, from which claims 7 and 11 depend.

The Examiner has clearly worked backwards from the claimed invention, using it as a "blueprint" to assemble unrelated bits and pieces from the prior art. There is no clear teaching in any of the references which would motivate one skilled in the art to provide a milk replacer for puppies which provides the claimed levels of nutrition which have been demonstrated to provide improved growth performance in puppies.

IV. Kinumaki et al. and Fujimori do not make up for the shortcomings in the primary references.

Kinumaki et al. has been cited for teaching a milk replacer for infant animals such as pigs and calves which contains amino acids. In rejecting claims 8 and 12, the Examiner has taken the position that it would have been obvious to include amino acids in a milk replacer for dogs. Again, one skilled in the art would not look to a milk replacer for pigs and calves to produce a milk replacer for puppies.

Fujimori has been cited against claims 10 and 13 for teaching a pet food for dogs and cats which may contain fructooligosaccharide. Again, Fujimori are not directed to milk replacer for dogs, but rather a pet food composition. Even if one were to incorporate the amounts of fructooligosaccharide taught in Fujimori, the claimed milk replacer would not result as none of the references teaches the claimed protein levels or the claimed ratio of casein and whey recited in claim 1, from which claim 10 depends. With regard to claim 13, applicant wishes to reiterate that none of the references teach the claimed levels of protein or lactose.

V. The Examiner's approach uses impermissible hindsight.

While applicants have repeatedly pointed out that human infant formulas or milk replacers for animals such as farm animals would not be suitable for use as a canine milk replacer, the Examiner has maintained that the use of the milk replacer for canines is merely an "intended use", asserting that it would have been obvious to apply the "known nutritional supplements" to a formula for any animal including puppies. The Examiner misses the point. The obviousness analysis cannot begin with the claimed composition which is then used to assemble unrelated bits and pieces of that composition from the prior art. That the intended uses of the prior art compositions relate to humans and farm animals is important in determining whether there is motivation in the prior art for their combination.

Applicant has clearly shown the importance of providing a canine milk replacer which closely duplicates the nutrient composition of actual bitch milk. The Examiner cannot choose to

ignore the fact that the composition of the present invention provides enhanced growth performance for puppies compared to other commercially available canine milk replacers.

VI. Conclusion

The proposed combination of references clearly does not render obvious the appealed claims as none of the references teach or suggest a milk replacer for puppies which includes the claimed levels of protein and the claimed ratio of casein and whey. Nor is there any teaching or suggestion in the prior art of record which would motivate one skilled in the art to modify the primary references to include the claimed levels as none of the references address the problem of the present invention, i.e., providing a milk replacer for puppies which is close to the nutrient composition of actual bitch milk.

Accordingly, no prima facie case of obviousness has been established with respect to any of the claims on appeal. The Board is requested to reverse the rejections of claims 1 and 3-14 in their entirety.

Respectfully submitted,

KILLWORTH, GOTTMAN, HAGAN & SCHAEFF, L.L.P.

By Susan M. Luna

Susan M. Luna
Registration No. 38,769

One Dayton Centre
One South Main Street, Suite 500
Dayton, Ohio 45402-2023
Telephone: (937) 223-2050
Facsimile: (937) 223-0724

SML/amm

APPENDIX

The Claims on Appeal

1. An artificially produced canine milk substitute composition comprising, on a dry matter basis, from about 35 to 45% protein, from about 25 to 35% fat, and from about 10 to 25% carbohydrates; wherein said protein comprises casein and whey in a weight ratio of about 70:30.

3. The composition of claim 1 comprising about 38% protein.

4. The composition of claim 1 comprising about 28% fat.

5. The composition of claim 1 comprising about 19% carbohydrates.

6. The composition of claim 1 in which the source of fat is selected from the group consisting of corn oil, canola oil, butter oil, arachidonic acid, docosahexaenoic acid, and blends thereof.

7. The composition of claim 1 containing fatty acids expressed as a percentage of total fatty acids on a dry matter basis, of from 15 to 19% palmitic acid, from about 5 to 9% stearic acid, from about 34 to 38% oleic acid, from about 17 to 21% linoleic acid, from about 1 to 4% α-linolenic acid, from about 0.5 to 2% arachidonic acid, from about 0.2 to 1% docosahexaenoic acid (DHA), from about 2 to 5% Omega 3 fatty acids, from about 18 to 22% Omega 6 fatty acids, and from about 1 to 4% trans fatty acids.

8. The composition of claim 1 containing amino acids expressed as a percentage of total essential amino acids on a dry matter basis of from about 6 to 10% arginine, 4 to 8% histidine, 8 to 12% isoleucine, 16 to 20% leucine, from about 13 to 17% lysine, from about 2 to 7% methionine, from about 6 to 10% phenylalanine, from about 8 to 12% threonine, from about 1 to 4% tryptophan, from about 9 to 13% valine, from about 2 to 5% cystine, and from about 2 to 6% tyrosine.

9. The composition of claim 1 containing from about 4 to 8% by weight lactose.

10. The composition of claim 1 containing about 0.50% by weight fructooligosaccharide.

11. The composition of claim 1 containing from about 27 to 37% by weight fatty acids.

12. The composition of claim 1 containing from about 15 to 25% by weight essential amino acids.

13. An artificially produced canine milk substitute composition comprising, on a dry matter basis, from about 35 to 45% protein, from about 25 to 35% fat, and from about 10 to 25% by weight carbohydrates, said composition further comprising from about 4 to 8% by weight lactose and about 0.50% by weight fructooligosaccharide.

14. An artificially produced canine milk substitute composition comprising, on a dry matter basis, from about 35 to 45% protein, from about 25 to 35% fat, and from about 10 to 25% carbohydrates, wherein the source of fat is selected from the group consisting of corn oil, canola oil, butter oil, arachidonic acid, docosahexaenoic acid, and blends thereof.